

**ASSEMBLY BILL**

**No. 1727**

---

**Introduced by Assembly Member Rodriguez**

February 14, 2014

---

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1727, as introduced, Rodriguez. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy that is owned by, or contracts with, the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards is eligible for donation to the repository and distribution program. Existing law also prohibits the donation of controlled substances to the repository and distribution program.

This bill would also prohibit the donation to a county repository and distribution program of a prescription drug that can be dispensed only to a patient registered with the drug's manufacturer in accordance with the requirements of the United States Food and Drug Administration.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California

1 State Board of Pharmacy prohibits an eligible or participating  
2 entity from participating in the program, it shall provide written  
3 notice to the prohibited entity within 15 days of making this  
4 determination. The county board of supervisors, the public health  
5 officer of the county, and the California State Board of Pharmacy  
6 shall ensure that this notice also is provided to one another.

7 (b) A county that elects to establish a repository and distribution  
8 program pursuant to this division shall establish written procedures  
9 for, at a minimum, all of the following:

10 (1) Establishing eligibility for medically indigent patients who  
11 may participate in the program.

12 (2) Ensuring that patients eligible for the program shall not be  
13 charged for any medications provided under the program.

14 (3) Developing a formulary of medications appropriate for the  
15 repository and distribution program.

16 (4) Ensuring proper safety and management of any medications  
17 collected by and maintained under the authority of a participating  
18 entity.

19 (5) Ensuring the privacy of individuals for whom the medication  
20 was originally prescribed.

21 (c) Any medication donated to the repository and distribution  
22 program shall comply with the requirements specified in this  
23 division. Medication donated to the repository and distribution  
24 program shall meet all of the following criteria:

25 (1) The medication shall not be a controlled substance.

26 (2) *The medication shall not be a prescription drug that can be*  
27 *dispensed only to a patient registered with the drug's manufacturer*  
28 *in accordance with the requirements of the United States Food*  
29 *and Drug Administration.*

30 ~~(2)~~

31 (3) The medication shall not have been adulterated, misbranded,  
32 or stored under conditions contrary to standards set by the United  
33 States Pharmacopoeia (USP) or the product manufacturer.

34 ~~(3)~~

35 (4) The medication shall not have been in the possession of a  
36 patient or any individual member of the public, and in the case of  
37 medications donated by a health or care facility, as described in  
38 Section 150202, shall have been under the control of a staff  
39 member of the health or care facility who is licensed in California

1 as a health care professional or has completed, at a minimum, the  
2 training requirements specified in Section 1569.69.

3 (d) Only medication that is donated in unopened, tamper-evident  
4 packaging or modified unit dose containers that meet USP  
5 standards is eligible for donation to the repository and distribution  
6 program, provided lot numbers and expiration dates are affixed.  
7 Medication donated in opened containers shall not be dispensed  
8 by the repository and distribution program and once identified,  
9 shall be quarantined immediately and handled and disposed of in  
10 accordance with the Medical Waste Management Act (Part 14  
11 (commencing with Section 117600) of Division 104).

12 (e) A pharmacist or physician at a participating entity shall use  
13 his or her professional judgment in determining whether donated  
14 medication meets the standards of this division before accepting  
15 or dispensing any medication under the repository and distribution  
16 program.

17 (f) A pharmacist or physician shall adhere to standard pharmacy  
18 practices, as required by state and federal law, when dispensing  
19 all medications.

20 (g) Medication that is donated to the repository and distribution  
21 program shall be handled in the following ways:

22 (1) Dispensed to an eligible patient.

23 (2) Destroyed.

24 (3) Returned to a reverse distributor or licensed waste hauler.

25 (4) (A) Transferred to another participating entity within the  
26 county to be dispensed to eligible patients pursuant to this division.  
27 Notwithstanding this paragraph, a participating county-owned  
28 pharmacy may transfer eligible donated medication to a  
29 participating county-owned pharmacy within another adjacent  
30 county that has adopted a program pursuant to this division, if the  
31 pharmacies transferring the medication have a written agreement  
32 between the entities that outlines protocols and procedures for safe  
33 and appropriate drug transfer that are consistent with this division.

34 (B) Medication donated under this division shall not be  
35 transferred by any participating entity more than once, and after  
36 it has been transferred, shall be dispensed to an eligible patient,  
37 destroyed, or returned to a reverse distributor or licensed waste  
38 hauler.

39 (C) Medication transferred pursuant to this paragraph shall be  
40 transferred with documentation that identifies the drug name,

1 strength, and quantity of the medication, and the donation facility  
2 from where the medication originated shall be identified on  
3 medication packaging or in accompanying documentation. The  
4 document shall include a statement that the medication may not  
5 be transferred to another participating entity and must be handled  
6 pursuant to subparagraph (B). A copy of this document shall be  
7 kept by the participating entity transferring the medication and the  
8 participating entity receiving the medication.

9 (h) Medication that is donated to the repository and distribution  
10 program that does not meet the requirements of this division shall  
11 not be distributed or transferred under this program and shall be  
12 either destroyed or returned to a reverse distributor. This  
13 medication shall not be sold, dispensed, or otherwise transferred  
14 to any other entity.

15 (i) Medication donated to the repository and distribution program  
16 shall be maintained in the donated packaging units until dispensed  
17 to an eligible patient under this program, who presents a valid  
18 prescription. When dispensed to an eligible patient under this  
19 program, the medication shall be in a new and properly labeled  
20 container, specific to the eligible patient and ensuring the privacy  
21 of the individuals for whom the medication was initially dispensed.  
22 Expired medication shall not be dispensed.

23 (j) Medication donated to the repository and distribution program  
24 shall be segregated from the participating entity's other drug stock  
25 by physical means, for purposes including, but not limited to,  
26 inventory, accounting, and inspection.

27 (k) A participating entity shall keep complete records of the  
28 acquisition and disposition of medication donated to, and  
29 transferred, dispensed, and destroyed under, the repository and  
30 distribution program. These records shall be kept separate from  
31 the participating entity's other acquisition and disposition records  
32 and shall conform to the Pharmacy Law (Chapter 9 (commencing  
33 with Section 4000) of Division 2 of the Business and Professions  
34 Code), including being readily retrievable.

35 (l) Local and county protocols established pursuant to this  
36 division shall conform to the Pharmacy Law regarding packaging,  
37 transporting, storing, and dispensing all medications.

38 (m) County protocols established for packaging, transporting,  
39 storing, and dispensing medications that require refrigeration,  
40 including, but not limited to, any biological product as defined in

1 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),  
2 an intravenously injected drug, or an infused drug, shall include  
3 specific procedures to ensure that these medications are packaged,  
4 transported, stored, and dispensed at appropriate temperatures and  
5 in accordance with USP standards and the Pharmacy Law.

6 (n) Notwithstanding any other provision of law, a participating  
7 entity shall follow the same procedural drug pedigree requirements  
8 for donated drugs as it would follow for drugs purchased from a  
9 wholesaler or directly from a drug manufacturer.